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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,742	04/18/2001	Henry Daniell	1465-PCT-US-00	6296

7590 01/09/2003

Schnader Harrison Segal & Lewis
IP Department 36th Floor
1600 Market Street
Philadelphia, PA 19103

EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,742

Applicant(s)

DANIELL, HENRY

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 8, 12-16, 27 and 29-32, drawn to a plastid transformation vector comprising a biopolymer-proinsulin fusion protein gene, plants and plastids transformed with the vector, and a method for producing those plants.

Group II, claim(s) 2 and 6-7, 12-16, 27 and 29-32, drawn to a plastid transformation vector comprising a cholera toxin B-subunit proinsulin fusion protein gene, plants and plastids transformed with the vector, and a method for producing those plants.

Group III, claim(s) 3-4, 12-16, 27 and 29-32, drawn to a plastid transformation vector comprising a heterologous DNA, plants and plastids transformed with the vector, and a method for producing those plants.

Group IV, claim(s) 5, 12-16, 27 and 29-32, drawn to a plastid transformation vector comprising a Cry2aA2 operon, plants and plastids transformed with the vector, and a method for producing those plants.

Group V, claim(s) 9-11, 12-16, 26-27 and 29-32, drawn to a plastid transformation vector comprising a gene for a protein based polymer fused to a biologically active molecule, plants and plastids transformed with the vector, and a method for producing those plants.

Group VI, claim(s) 17, 20, 27 and 37, drawn to a plastid transformation vector encoding

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an interferon and a method for transforming plants with the vector.

Group VII, claim(s) 18, 21, 27 and 37, drawn to a plastid transformation vector encoding an insulin-like growth factor and a method for transforming plants with the vector.

Group VIII, claim(s) 19, 22 and 27, drawn to a plastid transformation vector encoding human serum albumin and a method for transforming plants with the vector.

Group IX, claim(s) 23-25 and 27, drawn to a plastid transformation vector encoding cholera toxin B-subunit and an edible plant transformed with that plasmid and a method for transforming plants with the vector.

Group X, claim(s) 28 and 30, drawn to a process for recovering a biopolymer by using the reversible property of the biopolymer.

Group XI, claim(s) 33-35, drawn to a plastid transformation vector encoding insulin.

Group XII, claim(s) 36, drawn to a plastid transformation vector encoding a chaperonin and a promoter fusion protein.

Claims 12-16, 27, 29-32 and 37 will be examined to the extent they read on the elected invention.

2. The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: they do not share a special technical feature. The process of recovering a biopolymer of Group X makes no use of the plastid transformation vectors of Groups I-IX and XI-XII.

Groups I-IX and XI-XII share the technical feature that they are plastid transformation vectors comprising a plastid promoter, a selectable marker sequence, a nucleic acid encoding a

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protein, a transcription termination region, and spacer flanking sequences that are homologous to plastid DNA. However, this technical feature is not special because it does not constitute an advance over the prior art. Blowers et al (WO 99/05265) teach a plastid transformation vector comprising an expression cassette comprising the petunia plastid 16S rDNA promoter, a selectable marker coding sequence, *aadA*, a heterologous nucleic acid encoding GUS or HPH, and the *psbA* transcriptional termination region and flanking the expression cassette regions of homology to the petunia chloroplast genome (Figure 3, and pg 46-53). Thus, the technical feature is not special.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Rules

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3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from all references to GVGVP in the specification, the sequences on pg 30, lines 4-5, pg 34, second to last line, pg 78, paragraph 4 and claim 10. These sequences have also not been submitted in a paper copy of the sequence listing or by computer readable form.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
January 7, 2003



AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600